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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,357	03/01/2002	Sivaram Pillarisetti	18631-0141 (45115-268551)	7257
26158	7590	05/12/2005	EXAMINER	
WOMBLE CARLYLE SANDRIDGE & RICE, PLLC P.O. BOX 7037 ATLANTA, GA 30357-0037			HADDAD, MAHER M	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/091,357

Applicant(s)

PILLARISETTI, SIVARAM

Examiner

Maher M. Haddad

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2005 and 29 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 17-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/29/05&5/13/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 3/4/05, is acknowledged.
2. Claims 1, 3-5 and 17-24 are pending and under examination.
3. In view of the amendment filed on 3/4/05, only the following rejections are remained.
4. Applicant's IDS, filed 3/29/05 and 5/13/02 (page 2 of 3), is acknowledged, only references 14 and 16 were considered in the IDS filed on 5/13/02 since the rest of the references were considered on 11/30/04.
5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 1, 3-5 and 17-24 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting a compound that affects (Smooth Muscle Cell) SMC proliferation comprising adding a compound having unknown cellular proliferative activity to a first cell culture, measuring the amount of HSPG in the first cell culture; and comparing the amount of HSPG in the first cell culture to the amount of HSPG in a second cell culture not treated with the compound, does not reasonably provide enablement for a method for detecting compounds that affect any "cell proliferation" comprising adding a compound having unknown cellular proliferative activity to a first cell culture; measuring the amount of HSPG in the first cell culture, and comparing the amount of HSPG in the first cell culture to the amount of any HSPG in a second cell culture not treated with the compound in claim 1, wherein the HSPG is syndecan or glypican in claims 3 and 23-24, wherein the first cell culture and second cell culture are grown in serum-free media in claim 21. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim for the same reasons set forth in the previous Office Action mailed 11/30/04.

Applicant's arguments, filed 3/4/05, have been fully considered, but have not been found convincing.

While applicant asserts that Vascular SMCs express syndecans 1, 2 and 4, glypican-1 and perlecan, yet claiming a method for detecting a compound that affects any "cell" proliferation. Applicant has not address the issue of what type of cells produce syndecan, glypican or perlecan other than SMC.

Applicant argues that one of skill in the art would understand that a similar process of immunoprecipitation of could be used for the measurement of syndecan and glypican. However,

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the specification fails to provide an antibody that binds either syndecan or glypican and immunoprecipitate them. In the absence of such antibodies the skilled artisan would not be able to measure the syndecan or glypican nor discriminate between prelecan, syndecan or glypican when measuring the amount of HSPGs.

Regarding the molecule applicant argues that a person may use the methods of the present invention to determine the effect of any molecule or compound on cell proliferation. Applicant concludes that the identity of the molecule depends entirely on the inquiry performed by the end user of the invention.

However, in order to practice the claimed method the skilled artisan needs to know the chemical and physical properties of the molecule to be screened.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3-5, 17, 19 and 22 stand rejected under 35 U.S.C. 102(b) as being anticipated by Paka *et al* (abstract Nov. 2, 1999) for the same reasons set forth in the previous Office Action mailed 11/30/04.

Applicant's arguments, filed 3/4/05, have been fully considered, but have not been found convincing.

Applicant directs the examiner's attention to the specification on page 5, lines 21-23 which discloses that although it is currently believed that endothelial HSPGs inhibit SMC proliferation, it is not known whether SMC synthesize antiproliferative HSPGs that act as autocrine inhibitors. Applicant argues that while it was hypothesized that HSPGs may play a role in inhibition of cellular proliferation, the mechanism remained unclear. Applicant further argues that only after the disclosure of Applicant's invention was it known that SMCs naturally regulate the induction of HSPGs to maintain quiescence (Examples I and II). Applicant contends that Paka does not disclose or suggest that cells naturally regulate and synthesize HSPGs that act as autocrine inhibitors. Applicant concludes that absent this significant piece of information, Paka does not reasonably teach or suggest a method for detecting compounds which affect cellular proliferation by measuring their effect on HSPG production. Furthermore, Applicant submits that one of skill in the art would have to unduly experiment to discover that SMCs regulate cellular proliferation by inducing HSPG production. Applicant concludes that Paka does not teach or suggest the claimed invention.

However, it appears that applicant and the examiner differ on interpretation of both the claimed methods and the prior art. Also, applicant relies upon an asserted mechanism of action but does

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not provide objective evidence that the prior art teaching of same compound that affect the same cell proliferation and measuring same HSPG to achieve the same screening method differs from the claimed methods.

The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Even though applicant has proposed the mechanism by which HSPGs inhibits SMC proliferation does not appear to distinguish the prior art teaching the same methods to achieve the same end result. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In *re Wiseman*, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In *re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Again, there is no objective evidence of record that show whether the asserted claimed HSPGs inhibit or do not inhibit cell proliferation.

Therefore, it is clear that both Paka et al. and applicant add the same compound to the same cells to achieve the same screening results by measuring the amount to HSPG. The instant methods do not negate or preclude the mechanism of action indicated by the prior art nor does applicant provide objective evidence to distinguish the prior art from the claimed invention.

9. Claims 1, 3-5, 17, 19-20 and 22-23 stand rejected under 35 U.S.C. 102(b) as being anticipated by Paka *et al* (JBC, Dec. 1999, IDS Ref. No. 22) for the same reasons set forth in the previous Office Action mailed 11/30/04.

Applicant's arguments, filed 3/4/05, have been fully considered, but have not been found convincing.

Applicant restates the same arguments above. Further applicant emphasizes that Paka does not disclose or suggest that cells naturally regulate and synthesize HSPGs that act as autocrine inhibitors. Applicant contends that absent this significant piece of information, Paka cannot reasonably teach or suggest a method for detecting compounds which affect cellular proliferation by measuring their effect on HSPG production. Applicant concludes that Paka does not teach or suggest the claimed invention.

However, the mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Even though applicant has proposed the mechanism by which HSPGs inhibits SMC proliferation does not appear to distinguish the prior art teaching the same methods to achieve the same end result. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In *re Wiseman*, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of

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its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

10. Claims 1, 3-5, 17, 19-20 and 22 stand rejected under 35 U.S.C. 102(b) as being anticipated by Obunike *et al* (Jan 2000) as is evidenced by Paka *et al*, JBC, IDS Ref. No. 22) for the same reasons set forth in the previous Office Action mailed 11/30/04.

Applicant's arguments, filed 3/4/05, have been fully considered, but have not been found convincing.

Applicant restates the discussion above as it relates to both Paka references. Applicant submits that only after the disclosure of Applicant's invention was it known that SMCs naturally regulate that induction of HSPGs to maintain quiescence. Further, Applicant submits that while it was hypothesized that HSPGs may play a role in inhibition of cellular proliferation, the mechanism remained unclear. Furthermore, Applicant contends that Obunike does not disclose or suggest that cells naturally regulate and synthesize HSPGs that act as autocrine inhibitors. Applicant submits that Obunike fails to disclose or suggest that cells naturally regulate and synthesize HSPGs that act as autocrine inhibitors. Absent this significant piece of information, neither Obunike nor Paka, either alone or in combination, reasonably teach or suggest a method for detecting compounds which affect cellular proliferation by measuring their effect on HSPG production.

However, the mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Even though applicant has proposed the mechanism by which HSPGs inhibits SMC proliferation does not appear to distinguish the prior art teaching the same methods to achieve the same end result. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 3 and 23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Paka *et al* (abstract Nov. 2, 1999) or Obunike *et al* in view of Paka *et al* (JBC, Dec. 1999, IDS Ref. No. 22) for the same reasons set forth in the previous Office Action mailed 11/30/04.

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Applicant's arguments, filed 3/4/05, have been fully considered, but have not been found convincing.

Applicant traverses the rejection on the bases that neither of the references describe or suggest that SMCs naturally regulate the induction of HSPGs to maintain quiescence and act as autocrine inhibitors. Applicant contends that absent this significant piece of information in the cited references either alone or in combination; do not reasonably suggest a method for detecting a compound, which affects cellular proliferation by measuring their effect on HSPG production.

However, neither the cell quiescence phase nor the HSPGs induction act as autocrine is claimed and therefore, applicant arguments do not address the issues at hand and therefore, is considered irrelevant to the claimed invention.

13. Claims 1, 3 and 24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Paka *et al* (abstract Nov. 2, 1999) or Paka *et al* (Dec. 1999, IDS Ref. No. 22) or Obunike *et al* in view of U.S. Pat. No. 6,306,613 for the same reasons set forth in the previous Office Action mailed 11/30/04.

Applicant's arguments, filed 3/4/05, have been fully considered, but have not been found convincing.

Applicant submits that the '613 patent filing date is October 23, 2001, which does not antedate the march 2, 2001 priority date of the present application. Applicant concluded that the '613 patent cannot properly be applied as prior art under 103.

Contrary to applicant assertions, the '613 patent filing date is December 1, 1999 and the issue date is October 23, 2001. The patent's effective filing date in the U.S. is before the date that the claimed invention was invented by applicant. Therefore, the reference qualifies as prior art under 102(e) date.

14. No claim is allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad, Ph.D.
Patent Examiner
May 4, 2005


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